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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,739	12/10/2003	John P. Carulli	032796-217	5366
21839	7590	08/09/2006	EXAMINER	
BUCHANAN, INGERSOLL & ROONEY PC POST OFFICE BOX 1404 ALEXANDRIA, VA 22313-1404			QIAN, CELINE X	
			ART UNIT	PAPER NUMBER

1636

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/731,739	Applicant(s) CARULLI ET AL.	
	Examiner Celine X. Qian Ph.D.	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-8,14,15,22-25 and 80-100 is/are pending in the application.
4a) Of the above claim(s) 14,15,22-25 and 80 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,2,4,6,7,81-83 and 88-96 is/are allowed.
- 6) ☒ Claim(s) 5,8,84-89 and 97-100 is/are rejected.
- 7) ☒ Claim(s) 86 and 87 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1203,704,1004,1105</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1, 2, 4-8, 14, 15, 22-25, 80-100 are pending in the application.

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on 6/8/06 is acknowledged.

The traversal is on the ground(s) that the Office fails to show a serious burden to search all eleven groups of invention in a single application. Applicants further argue that some of the groups are classified in the same class, thus a search of those groups would not be burdensome. This is not found persuasive because the inventions are distinct for reasons set forth in the office action mailed on 4/20/06. It would have been burdensome to search all the groups together because the divergent subject matter which are covered by the different groups as shown by their different classification (different class or subclass). Although some of the groups fall within the same class such as 536, 424 and 530, Applicants are reminded that each of the class now encompasses a large amount of literature of different subject matter ranging from nucleic acid not used in recombinant technology and those which are used in recombinant technology (536), or cancer cells or components (424/277.1) and bioaffecting antibodies (424/130.1). As such, even some of the inventions are classified in the same class, they belong to different subclasses, and a search of all the inventions in the same class would still be burdensome because the search would not be co-extensive.

The requirement is still deemed proper and is therefore made FINAL.

Accordingly, claims 14, 15, 22-25 and 80 are withdrawn from consideration for being directed to non-elected subject matter. Claims 1, 2, 4-8 and 81-100 are currently under examination.

Claim Objections

Claims 86 and 87 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The parent claims (84 or 85) recites a "bone cell." Claims 86 and 87 recites that the bone cell is a mesenchymal stem cell, osteoclast, osteoblast or a chondrocyte. However, mesenchymal stem cells are cells that can give rise to connective tissues, lymphatics, bone, and cartilage cells, and chondrocytes are not bone cells. As such, claims 86 and 87 do not further limit their parent claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 88, 89 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 5, the recitation of "A replicative cloning vector comprising...a replicon operative in an isolated host cell" renders the claim indefinite because it is unclear whether the vector is operative or the replicon is operative in an isolate host cell. Appropriate clarification is needed. Claims 88 and 89 are rejected for same reason because they depend on claim 5.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection

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is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 8, 84-87, 97-100 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 162-166 of copending Application No. 10/374,979. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are all drawn to a host cell expressing a polypeptide comprising amino acid sequence of SEQ ID NO:3.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Claims 1, 2, 4, 6, 7, 81-83, 88-96 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X. Qian Ph.D. whose telephone number is 571-272-0777.

The examiner can normally be reached on 9:30-6:00 M-F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Celine X Qian Ph.D.
Examiner
Art Unit 1636

CELINE QIAN, Ph.D.
PRIMARY EXAMINER

